

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE: JOHNSON & JOHNSON
TALCUM POWDER PRODUCTS
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION

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) MDL Docket No. 2738
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This Document Relates To All Cases
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**DEFENDANTS JOHNSON & JOHNSON AND JOHNSON & JOHNSON
CONSUMER INC.'S MEMORANDUM OF LAW IN OPPOSITION TO
PLAINTIFFS' MOTION TO EXCLUDE THE OPINIONS OF ROBERT
KURMAN, M.D.**

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INTRODUCTION

Robert J. Kurman is an internationally recognized authority in the field of ovarian pathology. Given his prominence in the field, it is not surprising that plaintiffs do not challenge most of the opinions offered by Dr. Kurman in his expert report, including Dr. Kurman's descriptions of the morphologic, immunohistochemical and molecular genetic features of the various subtypes of epithelial ovarian cancer.¹ Instead, plaintiffs spend the majority of their brief attacking the biological plausibility opinions solicited by plaintiffs' counsel during Dr. Kurman's deposition.

Each of these attacks fails. *First*, plaintiffs' contention that Dr. Kurman's biological plausibility opinions should be excluded because they were not disclosed in his expert report both distorts the facts and ignores the law. Not only were these opinions discussed in Dr. Kurman's report in the context of his critiques of Dr. Kane, but courts are clear that opinions solicited by opposing counsel in the

¹ Plaintiffs do argue in passing that Dr. Kurman's explanation of the distinct pathologies of various subtypes of ovarian cancer is irrelevant to this litigation. Plaintiffs' lack of interest in these issues highlights the superficial and unscientific nature of their approach to the relevant science. As Dr. Kurman and several of defendants' other prominent cancer biology experts explain, "[i]t is highly unlikely that one agent, i.e., talc, is a cause of these different tumors, and there are no studies linking talc exposure to the specific genetic alterations associated with the development of these tumors." (Expert Report of Robert J. Kurman, M.D. ("Kurman Rep.") at 24, Feb. 25 2019 (attached as Ex. C37 to the Omnibus Certification of Julie L. Tersigni ("Tersigni Cert."), May 7, 2019 (ECF No. 9723-2)).)

course of a deposition do not need to be separately disclosed in an expert report.

Second, plaintiffs’ claim that Dr. Kurman’s biological plausibility opinions are unreliable *ipse dixit* ignores the substance of his report and testimony. Dr.

Kurman’s report – which relies on more than 100 references and contains more than 150 footnotes substantiating his opinions – addresses the relevant medical literature, including the studies that are the lynchpin of Dr. Sarah Kane’s opinions regarding biological plausibility. Moreover, Dr. Kurman is a prominent and widely published gynecological pathologist with more than four decades of experience reviewing ovarian tissue specimens. Dr. Kurman relied on both his understanding of the relevant scientific studies and his experience in offering his opinions that talc has not been shown to migrate to the ovaries or fallopian tubes or to cause the type of inflammatory response that could lead to ovarian cancer.

Plaintiffs also attack Dr. Kurman’s critiques of Dr. Kane, the only pathologist designated as an expert witness by plaintiffs. According to plaintiffs, Dr. Kurman’s criticisms are nothing more than “impermissible *ipse dixit*.”² Plaintiffs are wrong on this count too. Dr. Kurman’s critiques of Dr. Kane’s opinions regarding similarities between talc and asbestos, talc-induced chronic inflammation and migration are well-supported by dozens of scientific articles and

² (Pls.’ Steering Committee’s Mem. of Law in Supp. of its Mot. to Exclude the Ops. of Robert Kurman, M.D. (“Pls.’ Br.”) at 24, May 7, 2019 (ECF No. 9734-1).)

studies as well as Dr. Kurman's decades of experience reviewing tissue samples from patients with ovarian cancer.

For all these reasons, explained more fully below, plaintiffs' motion to exclude (in part) the opinions of Dr. Kurman should be denied.

BACKGROUND

A. Dr. Kurman's Background And Expertise

Dr. Kurman is an internationally recognized gynecologic pathologist with more than 40 years of experience in the field. Over the course of four decades, Dr. Kurman has served as: a Clinical Fellow at Harvard Medical School; Assistant Chief of the Department of Gynecology and Breast Pathology at the Armed Forces Institute of Pathology;³ assistant professor of pathology at the University of Southern California; professor of pathology and obstetrics and gynecology at the Georgetown University School of Medicine; and the Richard W. TeLinde Professor of Gynecologic Pathology at the Johns Hopkins University School of Medicine.⁴

Dr. Kurman's seminal contributions to the field of gynecologic pathology have led to more than \$16 million in federal research funding from the National

³ (Curriculum Vitae of Robert J. Kurman, M.D. ("Kurman CV") at 1-2 (Kurman Rep. Ex. A).)

⁴ (*Id.*)

Cancer Institute and Department of Defense.⁵ He has also received a number of awards for his contributions from numerous organizations, including the Memorial Sloan Kettering Cancer Center and the United States and Canadian Academy of Pathology.⁶ Dr. Kurman has served as the President of the International Society of Gynecological Pathologists and is an Honorary Fellow in both the Royal College of Pathologists and the Austrian Society of Pathologists.⁷

Dr. Kurman's prolific research career is reflected in his publication of 287 original papers, 154 review articles and book chapters and 15 books.⁸ He edited the 3rd, 4th and 5th editions and co-edited the 6th and 7th editions of Blaustein's *Pathology of the Female Genital Tract*, which is one of the premier textbooks on gynecologic pathology for medical trainees.⁹ He also co-edited the World Health Organization's *Classification of Tumours of Reproductive Organs* (4th Ed.).¹⁰ In addition to working on his own publications, Dr. Kurman has served as a reviewer for a number of high-impact journals, including the *New England Journal of*

⁵ (*Id.* at 57.)

⁶ (Kurman Rep. at 1.)

⁷ (*Id.*)

⁸ (*Id.*)

⁹ (Dep. of Robert J. Kurman, M.D. ("Kurman Dep.") 118:11-119: 9, Apr. 2, 2019 (attached as Ex. B44 to Tersigni Cert.).)

¹⁰ (Kurman Rep. at 1.)

Medicine, Journal of the American Medical Association and the *Journal of the National Cancer Institute*.¹¹

B. Dr. Kurman's Expert Opinions In This Litigation

Dr. Kurman's expert report, supported by 169 footnotes and a reference list containing more than 100 scientific publications, explains the pathology of various epithelial ovarian cancer subtypes and addresses flaws in the opinions of plaintiffs' only expert pathologist, Dr. Sarah Kane.

In the first half of his report, Dr. Kurman provides an overview of the various histological subtypes of epithelial ovarian cancer,¹² which is critical to any consideration of what causes these cancers. In the second part of his report, Dr. Kurman focuses on four opinions offered by plaintiffs' expert pathologist, Dr. Kane, and concluded that her opinions "reflect a misunderstanding of ovarian cancer pathology" and "are contrary to sound science."¹³

ARGUMENT

I. DR. KURMAN MAY OFFER OPINIONS ELICITED DURING HIS DEPOSITION.

Citing to Federal Rule of Civil Procedure 26, plaintiffs argue that the causation and biological plausibility opinions that Dr. Kurman offered during his

¹¹ (Kurman CV at 2-3.)

¹² (Kurman Rep. at 2-11.)

¹³ (*Id.* at 12-24.)

deposition should not be admitted because those opinions “were not disclosed in his report.”¹⁴ This argument should be rejected out of hand.

As an initial matter, plaintiffs are wrong that Dr. Kurman’s biological plausibility opinions were “not disclosed” in his expert report. For example, Dr. Kurman offers the following opinions in his report, all of which relate to biological plausibility:

- “[O]varian cancer is a diverse group of neoplasms (high-grade serous, low-grade serous, endometrioid, clear cell, seromucinous, and mucinous carcinomas and malignant Brenner tumors) with different morphology, pathogenesis, molecular genetic features and behavior that are distinct from mesothelioma. It is highly unlikely that one agent, i.e., talc, is a cause of these different tumors, and there are no studies linking talc exposure to the specific genetic alterations associated with the development of these tumors.”¹⁵
- “Dr. Kane overstates the significance of compositional similarities between talc and asbestos While talc and asbestos are both silicate minerals, talc is inert; by contrast, surface reactivity and the ability to release free radicals contribute to the pathogenic effects of asbestos.”¹⁶
- “[T]he studies that are cited [by plaintiffs’ experts] to support chronic inflammation as a cause of cancer are not relevant to talc-associated inflammation, because the type of inflammation cited is not the type of foreign body granulomatous inflammation associated with talc exposure.”¹⁷

¹⁴ (Pls.’ Br. at 3, 13-14, 16; *see also id.* at 21.)

¹⁵ (Kurman Rep. at 24.)

¹⁶ (*Id.* at 13.)

¹⁷ (*Id.* at 24.)

- “[I]f chronic inflammation plays a key role in the development of HGSC, the most common ovarian malignancy, one would expect to find evidence of inflammation associated with early precursor lesions [like STICs and p53 signatures]. . . . I have participated in a number of studies assessing the characteristics of STICs and have not found them to be associated with inflammation. . . . I have not seen inflammation associated with p53 signatures in the fallopian tube.”¹⁸
- “[O]bservations of talc in ovarian tissue do not support a conclusion of causation.”¹⁹
- “[T]here are no animal or histologic data supporting the genital migration of talc applied externally to the vulva.”²⁰
- “[E]ven when [foreign] particles are placed into the vagina, passage to the ovaries is quite unusual.”²¹
- “If talc exposure caused cancer, one would expect that some of the patients treated for benign conditions [with pleurodesis] would develop cancer in the future. Long-term studies have not demonstrated this to be the case.”²²
- “The evidence that serous ovarian cancer originates in the fallopian tubes invalidates many of Dr. Kane’s more specific opinions, since the biologic evidence she presents often relates to events occurring on the ovarian surface epithelium, implying that ovarian cancer originates there, rather than in the fallopian tubes.”²³

¹⁸ (*Id.* at 18.)

¹⁹ (*Id.* at 24.)

²⁰ (*Id.*)

²¹ (*Id.* at 22.)

²² (*Id.* at 24.)

²³ (*Id.* at 23.)

In short, there can be no question that Dr. Kurman's biological plausibility opinions are clearly set forth in his expert report, and plaintiffs' contentions to the contrary are meritless.

In any event, these opinions would still be admissible even if they had not been included in Dr. Kurman's expert report. As courts have recognized, "[w]hat is permissible trial testimony" hinges on "what occurred at the expert depositions." *In re Sulfuric Acid Antitrust Litig.*, 235 F.R.D. 646, 659 (N.D. Ill. 2006).

"Questions elicited at that time that go beyond the reports may well" expand the permissible scope of testimony allowed at trial. *Id.* This is because that sort of "responsive testimony is not the kind of ambush with an undisclosed opinion that the disclosure rules were designed to prevent." *Id.* at 659-60. Accordingly, where an opinion that is not contained in an expert's report is elicited by opposing counsel at a deposition, this "amount[s] to all the disclosure necessary under Rules 26(a)(2) and 37(c)(1)." *Id.* at 660 n.13; *see also, e.g., Spychalla v. Avco Corp.*, No. 2:12-6004-ER, 2014 WL 6736334, at *1 (E.D. Pa. Aug. 4, 2014) (declining to strike expert opinions elicited for the first time by counsel during the deposition; "nothing prohibits any counsel from questioning experts about (or based on) facts related to the case"); *Franklin v. United States*, No. CIV 12-1167 KBM/CG, 2014 WL 11497835, at *13 (D.N.M. Feb. 18, 2014) (refusing to exclude expert's opinion "not reflected in his expert report" but rather "elicited for the first time at

his deposition”); *Leichtenberg v. City of Leroy*, No. 10-1253, 2012 WL 13005640, at *7 (C.D. Ill. June 15, 2012) (denying motion to strike supplemental report based on new opinion formed as a result of questions posed by counsel at the deposition); *Wheeler v. Chrysler Corp.*, No. 98 C 3875, 2000 WL 263887, at *6 (N.D. Ill. Mar. 1, 2000) (refusing to strike expert’s causation opinion for plaintiff’s purported failure to properly disclose it pursuant to Rule 26; defense counsel “examined [plaintiff’s expert] at length about his opinion on causation” and therefore “was not prejudiced by the lack of disclosure in the Rule 26 report”). As one of these courts put it, “[p]laintiff’s counsel solicited the opinion”; “[s]he cannot now complain about that.” *Leichtenberg*, 2012 WL 13005640, at *7.

This Court should reach the same result. At the outset of his deposition, Dr. Kurman explained that – consistent with the opinions set forth in his report – his role was to “go over the issues of ovarian carcinogenesis from the standpoint of surgical pathology” and “review the plaintiffs’ expert gynecological pathologist’s report.”²⁴ When asked whether he intended to offer any opinions not contained in his report, Dr. Kurman explained that he did not intend to do so but would “have to hear the question” before answering definitively.²⁵ Over the course of his

²⁴ (Kurman Dep. 29:17-30:1.)

²⁵ (*Id.* 36:4-8.)

deposition, plaintiffs' counsel repeatedly asked Dr. Kurman about his opinions on both general causation and biological plausibility. For example:

Q. Tell me why you think talc doesn't cause – can't cause cancer.²⁶

Q. Do you have any opinions about whether exposure to talc could cause any type of reaction in any type of ovarian cells?²⁷

Q. If talc can cause p53 mutations in tubal cells, would you expect that it could also cause cancer?²⁸

Q. My question is, is it biologically plausible, in your opinion, that some type of inflammation can cause ovarian cancer?²⁹

Q. Do you agree that talc causes inflammation in epithelial ovarian cells?³⁰

Q. Do you believe asbestos can cause ovarian cancer?³¹

²⁶ (*Id.* 183:4-5.)

²⁷ (*Id.* 70:20-22.)

²⁸ (*Id.* 180:7-9.)

²⁹ (*Id.* 64:24-65:1.)

³⁰ (*Id.* 70:8-9.)

³¹ (*Id.* 77:19-20; *see also, e.g., id.* 57:19-21 (“Q. Is it your opinion that the notion that talc can cause chronic inflammation, which can cause ovarian cancer, is that process biologically plausible to you?”); *id.* 97:6-10 (“Q. My question is, do you have an opinion one way or the other whether asbestos exposure to ovaries -- do you have an opinion one way or the other whether it's biologically plausible that asbestos can cause ovarian cancer? Just do you have an opinion?”); *id.* 107:23-25 (“Q. Do you believe that talc can migrate from the perineum through a woman's reproductive tract to the ovaries?”); *id.* 165:7-10 (“Q. Do you believe that, over time, chronic inflammation in a particular part of gynecologic tissue can cause DNA damage and result in some type of gynecologic cancer?”).)

In view of plaintiffs' counsel's repeated questions about both causation and biological plausibility, counsel "cannot now complain" that Dr. Kurman offered opinions on those topics at his deposition. *Leichtenberg*, 2012 WL 13005640, at *7. And in the context of the Court's efforts to understand the scientific evidence relating to general causation, it would make little sense to prevent defense experts from responding to questions merely because, in preparing their expert reports, they failed to foresee plaintiffs' counsel's specific question. For this reason, too, plaintiffs' argument should be rejected.

II. DR. KURMAN'S BIOLOGICAL PLAUSIBILITY OPINIONS ARE RELIABLE.

Plaintiffs next argue that: (1) Dr. Kurman's biological plausibility opinions rest on an unreliable methodology and are based on Dr. Kurman's *ipse dixit*; and (2) Dr. Kurman employed an improper standard of certainty in rejecting plaintiffs' biological plausibility theory. As discussed further below, even a cursory review of the record refutes these arguments.

A. Dr. Kurman's Biological Plausibility Opinions Are Supported By Sound Scientific Methodology.

Plaintiffs first assert that Dr. Kurman's biological plausibility opinions are unreliable because: (1) he based them "primarily" on his experience; (2) he failed to review all the epidemiological literature involving talc and ovarian cancer; (3) his opinions are purportedly contradicted by a few sentences in a nearly-decade old

textbook that he edited; and (4) he did not conduct a full Bradford Hill analysis.³²

These arguments are all meritless.

1. Dr. Kurman's Opinions Are Properly Based On His Experience And The Relevant Scientific Literature, Not *Iipse Dixit*.

Plaintiffs are wrong that Dr. Kurman's reliance "primarily on his 'experience'" renders his biological plausibility opinions "nothing more than *ipse dixit*."³³

It is well settled that an expert's opinion may be "based primarily on experience" as long as that experience "provides a reasonable basis for his opinion" and "is applicable to the facts at hand." *Suter v. Gen. Accident Ins. Co. of Am.*, 424 F. Supp. 2d 781, 788 (D.N.J. 2006); *see also, e.g., Westley v. Ecolab, Inc.*, No. Civ.A.03-CV-1372, 2004 WL 1068805, at *6-7 (E.D. Pa. May 12, 2004) (rejecting argument that expert's opinions were unreliable because expert did not cite "any testing or peer-reviewed materials to support his theory"; "[o]pinions based solely on experience and knowledge are sufficient under *Daubert*") (citation omitted); *Integra Lifesciences Corp. v. HyperBranch Med. Tech., Inc.*, No. 15-819-LP-CJB, 2018 WL 1785033, at *6 (D. Del. Apr. 4, 2018) (denying motion to exclude expert testimony where expert relied on his "experiences" in forming his conclusion; "[w]hile [the expert's] explanation certain[ly] could have been more

³² (Pls.' Br. at 5-11.)

³³ (*Id.* at 5-6 (emphasis omitted).)

robust, [p]laintiffs’ concerns regarding the lack of data may be explored on cross-examination”). Thus, although a “trial court’s gatekeeping function requires more than simply ‘taking the expert’s word for it,’” expert testimony is admissible where the expert provides some explanation “as to why he came to [his] conclusion based on his personal experience.” *Integra Lifesciences Corp.*, 2018 WL 1785033, at *6 (citation omitted); *see also, e.g., Edison Wetlands Ass’n v. Akzo Nobel Chems., Inc.*, No. 08-419 (FSH), 2009 WL 5206280, at *4 (D.N.J. Dec. 22, 2009) (expert’s opinions were not impermissible *ipse dixit* where the expert’s “report and testimony reveal that” her opinions and any “assumptions” made in connection therewith were “based on available facts and reflect[ed] educated judgments that are sensibly explained”); *Del. Display Grp. LLC v. VIZIO, Inc.*, No. 13-2112-RGA, 2017 WL 784988, at *6 (D. Del. Mar. 1, 2017) (denying plaintiffs’ motion to strike defense experts’ testimony and finding that the statements at issue “are not *ipse dixit* testimony because they are based on [defense expert’s] experience and adequate facts”); *Poolworks, Inc. v. Aquafin, Inc.*, No. 2014-0037, 2016 WL 4544348, at *8 (D.V.I. Aug. 30, 2016) (finding that “[t]his case does not present an *ipse dixit* situation” because the expert relied on his extensive experience and observations to reach his conclusions).

Here, Dr. Kurman’s extensive experience and deep knowledge of ovarian cancer pathology provide a “reasonable basis” for his opinions related to plaintiffs’

biological plausibility theories. As the deposition testimony highlighted in plaintiffs' brief shows, Dr. Kurman has "spent 40 years looking at gynecologic pathology" as a surgical pathologist.³⁴ This includes reviewing "30 cases" involving ovarian cancer every "week or two weeks."³⁵ During those four decades, Dr. Kurman "read extensively and kept up with the literature," including the literature related to the pathology of ovarian cancer.³⁶ In light of his experience, it is no surprise that Dr. Kurman was tasked with editing the last four editions – and is currently editing the newest edition – of one of the most well-recognized and authoritative textbooks on the pathology of the female genital tract, and is also lead author for the World Health Organization's Classification of Ovarian Cancer.³⁷

In his report and over the course of his deposition, Dr. Kurman continually referred to this well of experience in explaining how he arrived at some of his conclusions. For example, he repeatedly referred to his knowledge of the medical literature in explaining his conclusions about inflammation.³⁸ Likewise, when

³⁴ (Pls.' Br. at 5 (citing Kurman Dep. 65:8-66:5).)

³⁵ (Kurman Dep. 156:21-23.)

³⁶ (*Id.* 65:13-14; *id.* 9:5-11.)

³⁷ (*Id.* 65:14-18, 118:11-119:12.)

³⁸ (*Id.* 51:11-17 ("In the literature, talc has been used in a variety of situations where it's caused foreign-body giant cell granulomatous inflammation."); *id.* 58:1-3 ("[B]ased on my experience and my reviewing of the literatures up to this point, talc induces a specific type of chronic inflammation"); *id.* 62:25-63:3 ("Insofar as what the literature has described about the type of inflammation

(*cont'd*)

pressed to explain his opinion that the type of inflammatory response implicated with talc exposure – foreign body giant cell granulomas – is only rarely observed in ovarian cancer, Dr. Kurman testified:

I've spent, as I said, 40 years looking at gynecologic pathology specimens, including a large number of ovarian cancers, and I have never seen a foreign body – I've seen a foreign-body giant cell reaction in rare ovarian tumors, endometrial carcinomas, due to extrusion of keratin, which can produce a foreign-body giant cell reaction. That, I've seen. I've seen teratomas, nothing to do with the litigation we're talking about now. It's a completely different kind of tumor. It's a germ cell tumor. And I've seen, with extrusion of keratin in those instances, a foreign-body giant cell reaction. Apart from those instances and maybe suture granulomas, which, again, are pretty obvious, I haven't seen that type of reaction in association with ovarian cancer during my entire career.³⁹

Courts have routinely found that these kinds of explanations, premised on experience and “reflect[ing] educated judgments that are sensibly explained,” *Edison Westlands Ass'n*, 2009 WL 5206280, at *4, are based on a “reliable method” and constitute admissible expert testimony, *Suter*, 424 F. Supp. 2d at 788

(cont'd from previous page)

induced by talc, which has never shown any evidence of causing cancer, I would say it's not plausible.”.)

³⁹ (*Id.* 59:21-60:12; *see also* Kurman Rep. at 16 (“Notably, I have examined a number of surgical pathology specimens from plaintiffs in talc litigation and have not observed foreign body granulomas or foreign body granulomatous inflammation associated with alleged talc use. Indeed, in the course of my 40 years of looking at microscopic slides of ovarian cancer, I have only seen foreign body granulomatous inflammation associated with ovarian tumors very rarely.”).)

(opinion based on expert’s “many years of professional experience treating valve recipients” and research in the area was admissible); *see also, e.g., Westley*, 2004 WL 1068805, at *6-7 (opinion “primarily based on [expert’s] experience and knowledge of chemicals and specifically his knowledge of aluminum hydroxide and potassium hydroxide and their potential effects on human tissue” met requirements of *Daubert*, notwithstanding expert’s failure to rely on any testing or literature).

In any event, Dr. Kurman’s opinions are also well supported by the relevant scientific literature in his field of expertise. For example, in addressing the flaws in plaintiffs’ migration and inflammation theories, Dr. Kurman comprehensively reviewed the materials cited in Dr. Kane’s report – as well as a number of other studies ignored by Dr. Kane – and explained that plaintiffs’ migration and inflammation theories are contrary to what is known in the scientific community about ovarian cancer pathology.⁴⁰ Regarding plaintiffs’ migration theory, for instance, Dr. Kurman pointed to a 2015 study demonstrating that tubal ligation “induces quiescence of distal fallopian tube epithelial cells,” casting doubt on plaintiffs’ claim that tubal ligation reduces the risk of talc-associated ovarian

⁴⁰ (See Kurman Rep. at 15-25.)

cancer by impeding talc's migratory path.⁴¹ And in discussing the plausibility of talc-induced inflammation as a cause of ovarian cancer, Dr. Kurman cited a study by Heller that found no evidence of response to talc particles (including no foreign body giant cell granulomas) in human ovarian tissue containing talc particles.⁴² Plaintiffs ignore these opinions and the scientific sources identified in Dr. Kurman's report, which provide a further underpinning for Dr. Kurman's opinions in this proceeding.

In sum, both Dr. Kurman's specific knowledge and experience as well as the literature discussed in his report provide a reliable basis for his biological plausibility opinions.

2. The Fact That Dr. Kurman Did Not Review Irrelevant Studies Does Not Render His Biological Plausibility Opinions Unreliable.

Plaintiffs' argument that Dr. Kurman's biological plausibility opinions are unreliable because he "failed to read and consider many of the major peer-reviewed studies on talc and ovarian cancer" also rings hollow. The vast majority of the studies that plaintiffs claim Dr. Kurman should have read are

⁴¹ (*Id.* at 23-24 (citing Tiourin et al., *Tubal ligation induces quiescence in the epithelia of the fallopian tube fimbria*, 22 *Reprod Sci.* 1262 (2015) ("Tiourin 2015"))).

⁴² (*Id.* at 22-23 (citing Heller et al., *The relationship between perineal cosmetic talc usage and ovarian particle burden*, 174 *Am. J. Obstet. Gynecol.* 1507 (1996) ("Heller 1996 – Talc"))).

epidemiological studies and meta-analyses examining the association between talc use and ovarian cancer.⁴³ These studies would not provide any assistance to *a pathologist approaching biological plausibility*; rather, as Dr. Kurman explained, pathologists focus on “biological explanations” and evidence in “cellular studies or extracellular studies that could be incorporated with the human population studies . . . in supporting a particular argument.”⁴⁴ Therefore, it is not surprising that Dr. Kurman’s biological plausibility opinions are not premised on this body of scientific literature. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999) (setting forth principle that a testifying expert is held to the standard of “an expert in the *relevant* field”) (emphasis added).

3. Purported Contradictions Between Dr. Kurman’s Testimony And A Decade-Old Textbook Are A Matter for Cross-Examination, Not *Daubert*.

Plaintiffs next point to purported contradictions between Dr. Kurman’s opinions and statements in a pathology textbook that he edited as evidence that his opinions are “contrived, unsupported, and litigation driven.”⁴⁵ Specifically, plaintiffs contend that Dr. Kurman’s opinion that environmental carcinogens or other foreign materials cannot migrate from the vagina to the ovaries is

⁴³ (See Pls.’ Br. at 6-8 (pointing to studies by, among others, Terry, Penninkilampi, Schildkraut, Ness, Taher and the Health Canada Review).)

⁴⁴ (Kurman Dep. 44:21-45:2.)

⁴⁵ (Pls.’ Br. at 10-11.)

contradicted by two sentences in the 2011 edition of *Blaustein's Pathology of the Female Genital Tract* – one stating that tubal ligation reduces the risk of ovarian cancer because it prevents environmental carcinogens from entering the peritoneal cavity and coming into contact with tubal and ovarian tissue, and another stating that it has been “suggested” that inflammation potentially caused by introduction of foreign material through the vagina “play[s] an important role in ovarian carcinogenesis.”⁴⁶ Plaintiffs’ efforts to disqualify Dr. Kurman based on a few isolated sentences from a dated textbook are misplaced.

Courts are hesitant to rely on textbooks to evaluate the reliability of an expert’s proposed testimony because “medical textbooks by their nature are summaries of empirical research and therefore may contain inaccuracies and overgeneralizations.” *In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 423 n.159 (S.D.N.Y. 2005). For this reason, “medical texts provide no more support than the evidence upon which they rely.” *Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1046, 1052 (S.D. Ill. 2001); *cf. Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 542 (W.D. Pa. 2003) (“A second-hand statement in a treatise that merely recites anecdotal information from case reports can be no more reliable than the case reports themselves.”).

⁴⁶ (*Id.* at 10; Kurman Dep. 159:22-160:5.)

Here, a review of the “evidence” on which the textbook statements rely shows that these statements do nothing to cast doubt on Dr. Kurman’s testimony. The first statement – that tubal ligation prevents environmental carcinogens from coming into contact with tubal and ovarian tissue and therefore prevents ovarian cancer – is “a general statement” based on “what some people have allegedly reported.”⁴⁷ The sentence does not even contain any references to case reports or other medical studies – indeed, there is *no citation at all*.⁴⁸ Notably, in the seven years since the textbook’s publication in 2011, several studies have been published that demonstrate that cells on the distal end of the fallopian tubes are altered after tubal ligation.⁴⁹ These studies have shown that tubal ligation is associated with “a reduced presence and decreased proliferation of progenitor cells” and “compositional and functional changes.”⁵⁰ It is now understood that these changes – and not any protection from the purported effects of migration of environmental carcinogens – explain why tubal ligation reduces the risk of high grade serous carcinoma.⁵¹

⁴⁷ (Kurman Dep. 129:16; *id.* 128:10-13.)

⁴⁸ (*See id.* 129:14-15.)

⁴⁹ (Kurman Rep. at 23-24 (citing Tiourin 2015).)

⁵⁰ (*Id.* (quoting Tiourin 2015).)

⁵¹ Drs. Shih and Birrer similarly point to studies explaining that alteration of the tubal fimbriated ends is now thought to reduce “the carcinogenic events of fallopian tube epithelium and prevent[] the occurrence of ovarian cancer precursor

(*cont’d*)

Likewise, the evidence underlying Dr. Kane's other biological plausibility opinion – that inflammation of the ovary attributable to the introduction of foreign material plays an important role in ovarian carcinogenesis – is also nonexistent. Indeed, the article that first proposed this hypothesis concluded that “[f]urther observational and experimental data [were] needed to confirm the hypothesis.”⁵² Recent data have, if anything, tended to disprove it. For example, as Dr. Kurman posited in his report, if inflammation plays a role in the development of high grade serous carcinoma, “one would expect to find evidence of inflammation associated with early precursor lesions.”⁵³ But, although he has “participated in a number of

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lesions on the fallopian tubes.” (Expert Report of Ie-Ming Shih, M.D., Ph.D. at 16, Feb. 25, 2019 (attached as Ex. C20 to Tersigni Cert.) (citing Roy et al., *Fimbrio-ovarian relationship in unexplained infertility*, 60 *Gynec. Obstet. Invest.* 128 (2005) and Huang et al., *Mutagenic, surviving and tumorigenic effects of follicular fluid in the context of p53 loss: initiation of fimbria carcinogenesis*, 36 *Carcinogenesis* 1419 (2015)); see also Expert Report of Michael Birrer, M.D., Ph.D. at 10, Feb. 25, 2019 (attached as Ex. C33 to Tersigni Cert.) (noting that “recent data have demonstrated that there are dramatic effects on the cells at the distal end of the fallopian tube cells after a tubal ligation”) (citing Tiourin 2015).)

⁵² Ness & Cottreau, *Review: Possible Role of Ovarian Epithelial Inflammation in Ovarian Cancer*, 91(17) *J. Nat'l Cancer Inst.* 1459, 1464 (1999) (attached as Ex. A105 to Tersigni Cert.); see also Ness et al., *Factors Related to Inflammation of the Ovarian Epithelium and Risk of Ovarian Cancer*, 11 *Epidemiology* 111, 111. 115 (2000) (attached as Ex. A106 to Tersigni Cert.) (referring to “the hypothesis that inflammation may mediate ovarian cancer risk” and noting that their data do “not completely” support the hypothesis). Notably, the only textbook reference discussed at the deposition was an article from Dr. Ness. (Kurman Dep. 160:25-161:2.)

⁵³ (Kurman Rep. at 18.)

studies assessing the characteristics of” the immediate precursor of invasive high grade serous carcinoma – serous tubal intraepithelial carcinoma (“STIC”) – Dr. Kurman has “not found them to be associated with inflammation.”⁵⁴ Other recent studies are in accord.⁵⁵

In short, as Dr. Kurman explained, “[a] lot has changed since” the most recent edition of the Blaustein textbook was published, and scientists have “learned a lot since 2011.”⁵⁶ Textbooks, by their nature, lag science, and Dr. Kurman’s disagreements with isolated statements in a nearly-decade old text do not render his opinions inadmissible.

4. Plaintiffs’ Contention That Dr. Kurman’s Failure To Conduct A Full Bradford Hill Analysis Is A “Problem” Misperceives Defendants’ Burden Of Proof.

Plaintiffs also contend that “[a] problem with Dr. Kurman’s opinions regarding talc and ovarian cancer is that he did not perform the very analysis that he said was required.”⁵⁷ Specifically, plaintiffs argue that Dr. Kurman was required to consider the Bradford Hill criteria before reaching any conclusions

⁵⁴ (Id.)

⁵⁵ See Malmberg et al., *Serous tubal intraepithelial carcinoma, chronic fallopian tube injury, and serous carcinoma development*, 468 *Virchows Arch.* 707, 712 (2016) (attached as Ex. A91 to Tersigni Cert.) (concluding that “no significant correlation was made between serous carcinoma and histological signs of inflammation”) (cited in Kurman Rep. at 18).

⁵⁶ (Kurman Dep. 155:8-19.)

⁵⁷ (Pls.’ Br. at 12.)

about causation.⁵⁸ Plaintiffs’ argument fundamentally misperceives both the nature of Dr. Kurman’s opinions and the respective burdens of the parties with regard to expert evidence.

As an initial matter, plaintiffs’ insistence that Dr. Kurman consider each Bradford Hill factor before opining on causation misunderstands the scope of his opinions. Based on his experience as a gynecological pathologist, his understanding of the relevant medical literature and his review of Dr. Kane’s report (and the sources cited therein), Dr. Kurman concludes that “there is no *pathological, biological, and mechanistic evidence* to support the assertion that talc exposure can cause ovarian cancer.”⁵⁹ While “cancer biology and epidemiology . . . come into play,” this opinion is primarily based on “what is currently known about ovarian cancer *pathology*.”⁶⁰ Other factors – like whether there is strength or consistency of association between perineal talc use and any subtype of ovarian cancer, or whether a dose-response relationship exists – have no bearing on Dr. Kurman’s opinion. Accordingly, it makes no sense to require him to have considered them. *See In re Abilify (Aripiprazole) Prods. Liab. Litig.*, 299 F. Supp. 3d 1291, 1347 (N.D. Fla. 2018) (although biological-plausibility expert

⁵⁸ (*Id.* at 11-12.)

⁵⁹ (Kurman Dep. 268:12-18.)

⁶⁰ (*Id.* 219:13-18; Kurman Rep. at 24 (emphasis added).)

did not “perform a Bradford Hill or weight-of-the-evidence analysis of general causation,” his opinion did “not meaningfully depend” on that evidence and therefore did not preclude him from testifying as to the drug’s “biological mechanism of action”).

In any event, as the Third Circuit has explained, and as discussed in defendants’ Omnibus *Daubert* Opposition brief, the test for admissibility of defense experts is “different” because the burden of proving causation is one that “the defense d[oes] not bear.” *Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777, 786 (3d Cir. 1996). Accordingly, it is “entirely appropriate” for defense experts to merely “critique[] . . . [p]laintiffs’ experts’ evidence, methodologies, and conclusions,” and “[t]here is no requirement that a defense expert offer a competing general causation opinion.” *In re Abilify*, 299 F. Supp. 3d at 1368; *see also In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 418-19 (S.D.N.Y. 2016) (“[G]iven that [d]efendants’ experts are attempting to prove a negative—that secondary perforation does not exist—pointing to the absence of convincing studies or the weaknesses of studies on which [p]laintiffs rely, and evaluating them in light of their clinical experience, training and research, is in these circumstances a logical and valid approach.”); *In re Zyprexa Prods. Liab. Litig.*, 489 F. Supp. 2d 230, 285 (E.D.N.Y. 2007) (“It is worth noting in this respect that defendants’

experts have a less demanding task, since they have no burden to produce models or methods of their own; they need only attack those of plaintiffs’ experts.”).

Here, given that Dr. Kurman’s opinions about biological plausibility are “essentially, critiques of [p]laintiffs’ experts’ evidence, methodologies and conclusions,” he was not required to conduct a full causation analysis and analyze each Bradford Hill factor.⁶¹ Rather, he merely had to point to “the absence of convincing studies” and “evaluat[e] them in the light of [his] . . . experience.” *In re Mirena*, 169 F. Supp. 3d at 418-19. This is precisely what Dr. Kurman did with respect to plaintiffs’ migration and inflammation theories. For this reason, too, plaintiffs’ arguments for exclusion fail.

B. Plaintiffs’ Assertion That Dr. Kurman Applied A Heightened Standard Of Proof Mischaracterizes His Testimony.

Finally, there is no merit to plaintiffs’ claim that Dr. Kurman’s biological plausibility opinions should be excluded because “Dr. Kurman formed those opinions based on the application and utilization of an incorrect standard of

⁶¹ Notably, a number of plaintiffs’ experts – who, critically, do bear the burden of proof and are required to conduct a full causation analysis – purport to reach their causal conclusions without examining each Bradford-Hill factor or even considering the literature relevant to their field. For example, Dr. Ghassan Saed, plaintiffs’ cancer biologist, concludes that “Johnson’s Baby Powder can cause ovarian cancer” based on a single, deeply-flawed experiment. (Expert Report of Ghassan Saed, Ph.D. at 20, Nov. 16, 2019 (attached as Ex. C17 to Tersigni Cert.).) His report does not even mention Bradford Hill, much less contain an analysis of each of the nine factors.

certainty.”⁶² According to plaintiffs, Dr. Kurman’s purportedly “heightened” standard requiring “absolute certainty” on the question of causation “is not compatible with the civil law preponderance of evidence standard or with the definition of general causation.”⁶³ But Dr. Kurman has not applied any such standard.

A closer look at plaintiffs’ cherry-picked examples shows that plaintiffs conflate Dr. Kurman’s testimony that he finds plaintiffs’ evidence unpersuasive with some sort of heightened standard of proof requiring “absolute certainty.” For example, plaintiffs claim that Dr. Kurman’s response “to various questions exploring his causation opinions” was, “I can only say what I believe in . . . I am not convinced.”⁶⁴ But plaintiffs’ ellipses omit a critical qualification – that he can “only say what [he] believe[s] in *based on the scientific evidence*.”⁶⁵ Dr. Kurman goes on to explain:

In this case, I’m not convinced that the talc particles or the birefringent particles that are being shown in these figures are actually within the tissue as a result of them actually being engulfed or whether they are there as a possible – as a contaminant.⁶⁶

⁶² (Pls.’ Br. at 17.)

⁶³ (*Id.* at 18.)

⁶⁴ (*Id.* at 21 (emphasis omitted) (quoting Kurman Dep. 201:19-25).)

⁶⁵ (Kurman Dep. 201:19-20 (emphasis added).)

⁶⁶ (*Id.* 201:20-25.)

Plaintiffs also claim that Dr. Kurman’s response of “not necessarily” to a question about whether cells with damaged DNA can cause cancer indicates that Dr. Kurman “refused to even consider addressing the causation question on any basis other than absolute certainty.”⁶⁷ But, again, Dr. Kurman’s full response shows that he acknowledged that DNA damage can, in some circumstances, lead to cancer:

Q. And then cells with damaged DNA can become cancer cells, can’t they?

A. Not necessarily. Not all of them do. *Some might.*

Q. Well, would you agree that all cancers are borne out of some genetic disruption?

A. The issue is it plays a role in carcinogenesis. But DNA damage, in and of itself, does not invariably lead to malignant transformation.

Q. Right. But I’m asking the inverse of that question. You can’t have cancer without original DNA damage; right?

A. That’s – *DNA damage is part of the process of development of a carcinoma* . . . As far as I know, all cancers are part of – part of the development of cancer is dependent on damage – or I should say genotoxicity, which means damage in DNA in some form.⁶⁸

⁶⁷ (Pls.’ Br. at 18.)

⁶⁸ (Kurman Dep. 87:5-88:9 (emphases added).)

As the full context of Dr. Kurman's statement shows, far from requiring "absolute certainty," Dr. Kurman appropriately explained that DNA damage is necessary but not sufficient to cause cancer.

Plaintiffs also point to Dr. Kurman's response that he was "not convinced" that talc particles were being engulfed by macrophages in a photograph as further evidence of his supposed application of a "more onerous standard of certainty."⁶⁹ But far from requiring "certainty," Dr. Kurman was simply explaining that, in the face of repeated questions from plaintiffs' counsel as to whether the photograph in question depicted particles being engulfed by macrophages, he was unable to independently confirm the contents of the grainy black-and-white photograph:

Q. So do you agree with me that that's another photomicrograph showing birefringent particles being engulfed by macrophages?

A. Well, honestly, I can't tell *from this black-and-white photo* what they are. I see polarized light and I – I see polarized, you know, particles, but I don't see what they are.

Q. Do you agree that the eight authors are reporting those to be –

A. Well, maybe they are. But they reported that. I don't see it. I can't convince myself *on this picture* that –⁷⁰

⁶⁹ (Pls.' Br. at 20-21.)

⁷⁰ (Kurman Dep. 196:20-197:6 (emphases added); *id.* 197:18-20 ("I mean, they're showing this picture, but it's a gemish, black and white, some little white particles. I can't tell if it's a macrophage or not.").)

In short, plaintiffs’ arguments are nothing more than a game of rhetorical “gotcha” that rests on distortions of Dr. Kurman’s deposition testimony. For this reason, too, plaintiffs’ arguments should be rejected. *See TVIIM, LLC v. McAfee, Inc.*, No. 13-cv-04545-HSG, 2015 WL 4148354, at *3 (N.D. Cal. July 9, 2015) (rejecting an argument to exclude an expert based on statements “cherry-pick[ed] . . . [from the expert’s] deposition in an attempt to discredit his entire methodology” because “those statements in isolation do not reflect [the expert]’s overall opinion”).

III. DR. KURMAN’S CRITICISMS OF DR. KANE’S OPINIONS ARE ADMISSIBLE.

Plaintiffs also seek to exclude Dr. Kurman’s criticisms of Dr. Kane as unreliable. This argument also lacks merit and should be rejected.

Dr. Kurman devotes half his report to methodically criticizing four opinions offered by plaintiffs’ pathologist, Dr. Kane.⁷¹ Specifically, Dr. Kurman explains that: (1) Dr. Kane’s comparison of talc to asbestos – and of ovarian cancer to mesothelioma – “overstates” the similarities between the two and “fails to appreciate the important differences between these minerals and diseases”; (2) Dr. Kane’s view that talc causes chronic inflammation that leads to cancer fails to distinguish between specific types of inflammation and is not supported by the

⁷¹ (See Kurman Rep. at 12-24.)

evidence she cites; (3) Dr. Kane’s discussion of talc found in ovarian tissue is methodologically flawed because she used novel microscopy techniques and relied on a single case report; and (4) Dr. Kane’s opinion that talc can migrate to the ovary or fallopian tube is unsupported and undermined by the fallopian tube origin of serous carcinoma.⁷² Given these deficiencies, Dr. Kurman concludes, “[b]ased on [his] extensive experience studying ovarian cancer pathology,” that Dr. Kane’s opinions are “not scientifically justified” and are “inconsistent with the consensus view of the scientific community regarding what is currently known about ovarian cancer pathology.”⁷³

In response, plaintiffs claim that the majority of Dr. Kurman’s criticisms are based on nothing more than his “say so” and therefore should be excluded.⁷⁴ This argument fails for two reasons. First, as explained in Section II.A.1 above, it is perfectly appropriate for an expert to rely on his own experience in the relevant field in forming his opinions. Second, Dr. Kurman’s opinions are grounded in scientific literature, as set forth in great detail in his report and explained further below.

⁷² (*Id.*)

⁷³ (*Id.* at 24.)

⁷⁴ (Pls.’ Br. at 24-39.)

A. Dr. Kurman’s Criticisms Of Dr. Kane’s Comparison Of Talc And Asbestos – And Ovarian Cancer And Mesothelioma – Are Not Ipse Dixit.

Dr. Kurman first criticizes Dr. Kane’s opinion that the relationship between talc and ovarian cancer is analogous to the relationship between asbestos and mesothelioma.⁷⁵ Contrary to plaintiffs’ arguments, this criticism is far from *ipse dixit*.

Plaintiffs assert that Dr. Kurman’s opinion that talc is “‘inert’” and “‘thus does not mimic the pathogenic effects of asbestos’” is inconsistent with his claim that “talc can elicit an inflammatory response.”⁷⁶ According to plaintiffs, “[i]f Dr. Kurman cannot pick a position based on a scientific methodology, the opinions he gives on this topic are tantamount to *ipse dixit*.”⁷⁷ Plaintiffs’ argument misstates what constitutes *ipse dixit* testimony, presumably because they recognize that purported inconsistencies in an expert’s opinions are fodder for cross-examination, not exclusion. In any event, there is no actual inconsistency. As Dr. Kurman explained, IARC characterizes talc as “inert” because, unlike asbestos, it is not

⁷⁵ (Kurman Rep. at 12-15.)

⁷⁶ (Pls.’ Br. at 25.)

⁷⁷ (*Id.* at 25-26 (quoting Kurman Rep. at 14).)

chemically reactive.⁷⁸ This characterization of talc as inert has nothing to do with whether talc is capable of producing an inflammatory response; indeed, as Dr. Kurman testified, “inert particles induce a foreign-body giant cell reaction of the sort – similar to what talc does.”⁷⁹

Plaintiffs also take issue with Dr. Kurman’s criticisms of the asbestos occupational exposure studies cited by Dr. Kane,⁸⁰ arguing that Dr. Kurman never explained “why talc and asbestos are scientifically and medically incomparable.”⁸¹ But, in explaining why these studies are “not relevant” to this litigation, Dr. Kurman was not focused on the similarities or differences between talc and asbestos. Rather, Dr. Kurman’s point was that the occupational exposure studies involve “significant exposure” to asbestos via inhalation for “hours every day,” and that these “massive exposures” say little if anything about exposure through perineal use.⁸² Dr. Kurman further explained that studies involving occupational exposure to asbestos often include only a “small numbers of cases” because “most people who worked in the industry were men,” further undermining their

⁷⁸ (Kurman Rep. at 13 (citing Int’l Agency for Res. on Cancer, World Health Org., 100C *Monographs on the Evaluation of Carcinogenic Risks to Humans: Arsenic, Metals, Fibres, and Dust* 1.6 (2012)).)

⁷⁹ (Kurman Dep. 70:2-7.)

⁸⁰ (See Pls.’ Br. at 26.)

⁸¹ (*Id.*)

⁸² (Kurman Rep. at 14; *see also* Kurman Dep. 92:14-22.)

usefulness in the context of evaluating women’s talcum powder use.⁸³ In addition, while plaintiffs claim that Dr. Kurman’s opinion that many of the tumors observed in occupational studies were likely misclassified is based on nothing more than his “say[] so,”⁸⁴ Dr. Kurman in fact cited a meta-analysis “removing 20% of ovarian cancer cases” from every study it included in order to account for misclassification.⁸⁵

Finally, plaintiffs complain that Dr. Kurman “dismiss[ed] Dr. Kane’s observation about the visual similarities between talc-induced HGSC [i.e., high-grade serous ovarian carcinoma] and asbestos-induced mesothelioma” without providing “a description of the proper methodology for routine microscopic analysis.”⁸⁶ But Dr. Kurman, a world-renowned pathologist, has “40 years” of experience “looking at microscopic slides.”⁸⁷ This experience provides a more than sufficient basis for Dr. Kurman to reliably opine on whether an “experienced gynecological pathologist” would be able to “distinguish between HGSC and mesothelioma by morphology on routine microscopic analysis.”⁸⁸ For example,

⁸³ (Kurman Dep. 92:14-22.)

⁸⁴ (Pls.’ Br. at 26.)

⁸⁵ (Kurman Rep. at 14 n.98.)

⁸⁶ (Pls.’ Br. at 26-27.)

⁸⁷ (Kurman Rep. at 16.)

⁸⁸ (*Id.* at 14.)

Dr. Kurman points to an immunohistochemical marker that is “rarely expressed by serous carcinomas, but is expressed in the majority of mesotheliomas” and therefore used to differentiate the two diseases.⁸⁹ This expertise in pathology renders Dr. Kurman’s opinions regarding microscopically-observable differences between these tumors reliable. *See, e.g., Hurd v. Yaeger*, No. 3:06cv1927, 2009 WL 2516874, at *7 (M.D. Pa. Aug. 13, 2009) (opinions based “on decades of practice in obstetrics and gynecology” were reliable); *Adams v. Lab. Corp. of Am.*, 760 F.3d 1322, 1330 (11th Cir. 2014) (per curiam) (reversing district court’s exclusion of pathologist’s opinion based on her review of slides; expert “formed her opinion by using reliable tools, applying an established body of medical knowledge, and drawing on her extensive experience,” which was far from “an *ipse dixit* assessment”).⁹⁰

⁸⁹ (*Id.* (pointing to calretinin); *see also id.* at 14-15 (“Other immunohistochemical markers used to differentiate ovarian carcinomas from mesotheliomas include MOC31, PAX8, Claudin4, BER-EP4 and Estrogen Receptor.”).)

⁹⁰ Plaintiffs also suggest that Dr. Kurman’s criticisms of Dr. Kane must be excluded because Dr. Kurman “disavow[ed] his asbestos expertise.” (Pls.’ Br. at 24-25 & n.68.) But Dr. Kurman does not seek to offer opinions about “the different types of asbestos” or “the specifics of the composition of asbestos,” areas in which he acknowledges he “would defer to a mineralogist.” (*Id.* at 25 n.68 (quoting Kurman Dep. 90:8-12, 91:15-17).) Instead, his opinions are limited to explaining that the biological effects of asbestos and talc – which are structurally dissimilar – are “vastly different.” (Kurman Rep. at 13.)

For all of these reasons, Dr. Kurman’s critiques of Dr. Kane’s claim that talc and asbestos, as well as ovarian cancer and mesothelioma, are “similar” are reliably grounded on scientific principles and should not be excluded.

B. Dr. Kurman’s Criticisms Of Plaintiffs’ Inflammation Theory Are Not *Ipsa Dixit*.

Plaintiffs also take issue with Dr. Kurman’s conclusion that plaintiffs’ inflammation theory (as set forth in Dr. Kane’s report) is “speculative” and “not supported by sound science.”⁹¹ Plaintiffs again assert that Dr. Kurman provides “no basis” for his criticisms and that his opinions therefore amount to nothing more than *ipse dixit*.⁹² Once again, this argument is backwards; it is Dr. Kane whose opinions are speculation and *ipse dixit*, and Dr. Kurman properly concludes that this renders her opinions unreliable.

Plaintiffs’ arguments to the contrary are illogical. Plaintiffs first submit that Dr. Kurman’s opinion that the only “granulomatous inflammation” he has seen that was associated with ovarian cancer was in response to keratin production by the tumor and had “nothing to do with talc” should be excluded as *ipse dixit* because this opinion is “only” based on Dr. Kurman’s “40 years of looking at microscopic slides of ovarian cancer” – including “polarization of those ovarian tumors” to look

⁹¹ (Kurman Rep. at 15-20.)

⁹² (Pls.’ Br. at 27-30.)

for particulates.⁹³ As explained above, however, courts routinely find that opinions “formed . . . using reliable tools, applying an established body of medical knowledge, and drawing on . . . extensive experience” are reliable. *Adams*, 760 F.3d at 1330. Indeed, it is hard to imagine a more reliable source for Dr. Kurman’s pathology opinions than decades of reviewing pathology slides from women with ovarian cancer.⁹⁴

Plaintiffs next turn to Dr. Kurman’s observation that Dr. Kane was unable to point to any histologic evidence supporting the notion that talc exposure causes inflammation in the ovaries and speculated instead that this was because of a latency period.⁹⁵ Plaintiffs accuse Dr. Kurman of “offer[ing] no basis for this opinion,”⁹⁶ but this argument is a red herring. After all, Dr. Kane is the one who is relying on a supposed latency period to justify the lack of supporting evidence for her opinions. Therefore, she is the expert who needs support for her opinions, and

⁹³ (*Id.* at 28 (quoting Kurman Rep. at 16).)

⁹⁴ Plaintiffs also take issue more generally with Dr. Kurman’s opinion that “[f]oreign-body granulomas are what you would expect to find in tissue exposed to non-infection material, like talc.” (Kurman Rep. at 16; *see also* Pls.’ Br. at 37-39.) But even Dr. Kane agrees that granulomas “are in response to a foreign body” like “asbestos . . . or another type of fiber.” (Dep. of Sarah E. Kane, M.D. 328:13-329:3, Jan. 25, 2019 (attached as Ex. B45 to Tersigni Cert.); *see also* Expert Report of Sarah E. Kane, M.D. at 12, Nov. 15, 2018 (attached as Ex. C38 to Tersigni Cert.) (“Injecting talc into the pleural space causes an inflammatory and granulomatous reaction . . .”).)

⁹⁵ (Kurman Rep. at 16.)

⁹⁶ (Pls.’ Br. at 29.)

Dr. Kurman is merely calling her out for that rank speculation. Dr. Kurman does not need to cite to scientific literature to point out the fact that Dr. Kane has made up her opinions from whole cloth. And in any event, he does in fact point to scientific literature discussing the fact that talc use is habitual.⁹⁷ This literature further calls into question Dr. Kane's speculation that women would have used talc in their youth, experienced chronic inflammation at the time, stopped using talc, after which the inflammation purportedly disappeared, after which they contracted ovarian cancer. For plaintiffs to advance this speculative theory and accuse Dr. Kurman of speculation is remarkable.

Finally, plaintiffs complain that, while Dr. Kurman "states that there are differences" between inflammation caused by diseases like ulcerative colitis and talc-associated foreign body reactions, he "fails to give any basis for how those differences affect the propensity of each type of inflammation to lead (or not lead) to cancer development."⁹⁸ Quite the opposite, Dr. Kurman's report clearly states that inflammation from ulcerative colitis is "characterized by the presence of neutrophils, lymphocytes and plasma cells accompanied by features of mucosal injury and necrosis," which are not features of foreign body granulomatous

⁹⁷ (Kurman Rep. at 16 (citing Cramer et al., *The Association Between Talc Use and Ovarian Cancer: A Retrospective Case Control Study in Two US States*, 27 *Epidemiol.* 334 (2016)).)

⁹⁸ (Pls.' Br. at 29-30.)

inflammation.⁹⁹ Although plaintiffs may disagree with the significance of that conclusion, such disagreement is not a ground for concluding that Dr. Kurman's methods were unreliable or unsupported.

C. Dr. Kurman's Criticisms Of Plaintiffs' Migration Theories Are Not *Ipse Dixit*.

Finally, plaintiffs launch a series of attacks targeting Dr. Kurman's criticisms of plaintiffs' migration theories and reliance on studies purporting to find talc in ovarian tissue. According to plaintiffs, "[e]ach of . . . [Dr. Kurman's] opinions critical of Dr. Kane's opinion on the migration of talc to the ovaries lacks any basis other than the *ipse dixit* opinions of Dr. Kurman."¹⁰⁰

First, plaintiffs take issue with Dr. Kurman's rejection of Dr. Kane's opinion that talc found in ovarian pathology samples "provides additional evidence in support of a causal relationship" between talc use and ovarian cancer.¹⁰¹ As Dr. Kurman explains in his report, Dr. Kane's views are unsupported by the scientific literature, and her reliance on a handful of studies is misplaced.¹⁰² Plaintiffs insist that Dr. Kurman's critiques are inadmissible unless Dr. Kurman can also "set forth any facts or data" to show that talc found in tissue samples is "inconsistent with

⁹⁹ (Kurman Rep. at 18.)

¹⁰⁰ (Pls.' Br. at 32.)

¹⁰¹ (*Id.* at 30-32.)

¹⁰² (*See* Kurman Rep. at 20-21.)

causation” – i.e., unless Dr. Kurman can disprove causation.¹⁰³ But, as set forth in defendants’ memorandum in response to plaintiffs’ omnibus *Daubert* brief, courts have recognized that there “is no requirement that a defense expert offer a competing general causation opinion.” *In re Abilify*, 299 F. Supp. 3d at 1368. Rather, it is “entirely appropriate” for defense experts to merely “critique[] . . . [p]laintiffs’ experts’ evidence, methodologies, and conclusions.” *Id.* This is exactly what Dr. Kurman has done, and nothing more is required.

Second, plaintiffs contend that Dr. Kurman’s claim that tissue samples can easily be contaminated by talc must be rejected because Dr. Kurman does not cite to “medical literature” or offer “any methodology” to support his opinion.¹⁰⁴ Not so. Dr. Kurman points to a study by Heller that found no difference in the talc particles found in ovaries of women who frequently applied talc and those who reported no use.¹⁰⁵ As he explains, these findings could well be attributable to contamination, a conclusion “which is supported by the lack of any associated pathologic findings that would indicate actual biologic exposure.”¹⁰⁶ Moreover, Dr. Kurman’s opinions about the common contaminants in a pathology laboratory

¹⁰³ (Pls.’ Br. at 31.)

¹⁰⁴ (*Id.* at 34.)

¹⁰⁵ (Kurman Rep. at 22-23 (citing Heller 1996 – Talc).)

¹⁰⁶ (*Id.* (citing Heller 1996 – Talc).)

are all the more reliable in light of his 40 years of experience working in such a setting. *Suter*, 424 F. Supp. 2d at 788 (an expert opinion may be “based primarily on experience” so long as that experience “provides a reasonable basis for his opinion” and “is applicable to the facts at hand”).

Third, plaintiffs turn to Dr. Kurman’s opinion that, if plaintiffs’ inhalation theory were viable, “one would expect to see evidence of talc-induced pulmonary diseases in women who use perineal talc.”¹⁰⁷ Plaintiffs claim that Dr. Kurman offers “no support” for this opinion and it should therefore be excluded as *ipse dixit*.¹⁰⁸ But the only support for this opinion is the **absence** of reports showing lymphoma or other diseases in the lymphatic system in women who use perineal talc – and Dr. Kurman clearly states that he is not aware of such reports.¹⁰⁹ Notably, even plaintiffs’ own expert, Dr. Zelikoff, agrees that if talc could transport through the lymphatic system, then it should cause chronic inflammation “systematically” throughout the body,¹¹⁰ and plaintiffs’ experts have not identified a single study suggesting that it does.

¹⁰⁷ (Kurman Rep. at 23.)

¹⁰⁸ (Pls.’ Br. at 35-36.)

¹⁰⁹ (Kurman Rep. at 23.)

¹¹⁰ (Dep. of Judith Zelikoff, Ph.D. 306:2-307:1, Jan. 21, 2019 (attached as Ex. B31 to Tersigni Cert.).)

Finally, plaintiffs take umbrage with Dr. Kurman’s position that evidence that serous ovarian cancer originates in the fallopian tubes undermines Dr. Kane’s conclusions.¹¹¹ According to plaintiffs, because Dr. Kane believes that “proximal migration of talc is possible to either the ovaries or the fallopian tubes,” Dr. Kurman’s position does nothing to undermine Dr. Kane’s opinion.¹¹² But, the fallopian-tube origin of serous ovarian cancer does “invalidate many of Dr. Kane’s more specific opinions” because, as Dr. Kurman points out, the biologic evidence Dr. Kane cites “often relates to events occurring on the ovarian surface epithelium.”¹¹³ Indeed, Dr. Kane cites *no* studies involving the fallopian tube epithelium. Thus, far from “expect[ing] the Court and juries to take his word for it that Dr. Kane’s conclusion is [in]valid,” Dr. Kurman effectively “discredit[s]” Dr. Kane’s conclusions regarding talc migration by relying on scientifically grounded objections to her chain of reasoning. *Wilder v. Eberhart*, 977 F.2d 673, 676 (1st Cir. 1992) (reversing exclusion of defendant’s expert who failed to prove that an alternative cause was the more likely reason for the plaintiff’s injury; “the defendant need not disprove causation,” but need only “produce credible evidence which tends to discredit or rebut the plaintiff’s evidence”).

¹¹¹ (See Kurman Rep. at 23-24.)

¹¹² (Pls.’ Br. at 37.)

¹¹³ (Kurman Rep. at 23.)

CONCLUSION

For the foregoing reasons, the Court should deny plaintiffs' motion to exclude to opinions offered by Dr. Kurman.

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Respectfully submitted,

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